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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,005	06/28/2001	Hakuo Ikegami	IKEGAMI=2	6398
7590 03/24/2004 BROWDY AND NEIMARK, P.L.L.C. 624 Ninth Street, N.W. Washington, DC 20001-5303			EXAMINER HELMER, GEORGIA L	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 03/24/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/893,005

Applicant(s)

IKEGAMI ET AL.

Examiner

Georgia L. Helmer

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-16, 18-21 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16, 18-21 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 23 December 2003.
2. Applicant has cancelled claims 1-10, 17, and 22-30. Claims 11-16, 18, and 20-21 have been amended. New claim 32 has been added. Claims 11-16, 18-21 and 32 are pending, and are examined in the instant action. New claim 31, added in the amendment of 24 February 2003, was inadvertently overlooked and not entered. Claims 31 and 32 appear to be duplicate claims. Therefore, claim 31 will not be entered. The Office regrets any inconvenience to Applicant.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 second paragraph

6. Claims 11-16, 18-21 and 32 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

In claim 11,

- line 1, "grown-up" is indefinite and ambiguous. A "grown-up" plant can be a plant at any stage from germinating seed to seed-set and senescence.

Is this a flowering plant? Or a plant having seed? All subsequent recitations of this language are also rejected.

- line 4, "additional" regulatory sequence is unclear because no initial regulatory sequence is recited.

Claim 20 is unclear because Applicant lists various adjectives describing the plant product, namely "cut", "peeled", "pulverized", "squeezed", or "extracted", but does not state what is kept and what is discarded from any given step. For example, "extracted": if a plant is extracted by lyophilization, removing the water, and leaving the dehydrated plant material, the water removed is a product of the extraction.

In claim 21, "food composition lacks antecedent basis.

Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 102

7. Claims 11-16, 18-20 and 32 remain rejected under 35 USC 102 (b) as being anticipated by Goodman, et al (US #4, 956, 282, issued September 11, 1990), for reasons of record, which are repeated in part below. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Goodman teaches

- A transgenic plant produced from an edible plant (column 4, lines 57-60),

- transforming the plant with a DNA encoding a cytokine (column 3, line 20-30),
- of a mammalian origin (column 3, lines 11-30, and column 7, lines 27-33).
- mammalian cytokines (column 3, line 20-30),
- mammalian interferon, (column 3, line 20-30),
- where the origin of the protein is murine (column 7, lines 27-33),
- where the plant is Solanaceous (column 4, lines 55-63),
- where the plant is in the form of tissue isolated from the whole plant body (column 4, lines 55-63, column 5, lines 51-59)),
- where the plant is in a processed form obtainable by extracting (column 5, lines 46-50).

An "edible" plant is inherently a plant edible in its raw or uncooked condition.

A plant containing trehalose appears to be an inherent property of the claimed transgenic plant, especially Brassica, are known to produce trehalose naturally (Vogel et al, J Exper. Botany. 52, 1817-1826, 2001).

Applicant traverses saying primarily that their disclosure of Goodman (column 5, lines 40-60) the cited paragraph as expressed with the words "may be". That this means that the statements in the paragraph were made based on Goodman's hope or speculation and did not really on experimental results (Response, page 8). Applicant further traverses that Goodman's experimental results do not refer to "grown-up" plants, rather the results stop at the stage where callus is obtained.

Applicant's traversal is unpersuasive. The term "grown-up" in "grown-up" plants is ambiguous and unclear, as discussed above in the 112.2 section. Accordingly, this term is given no patentable weight. Furthermore, Applicant's assert (Response, page 9) that actually obtaining a grown-up plant from callus requires undue experimentation, and cites three documents. Applicant does not recite any particular steps from callus to plant, as argued. Therefore, if Goodman is not enabled, neither is Applicant's claimed invention.

Applicant traverses saying primarily that (response, page 10) claims 11 is amended to clarify that a DNA sequence being introduced has an additional constitutive regulatory sequence, inducible regulatory sequence, or tissue-specific regulatory sequence. Applicant's traversal is unpersuasive. The term "additional" is indefinite and unclear, as discussed above in the 112.2 section. Therefore, this term is given no patentable weight.

Applicant claims (claim 11, lines 11-13) and all claims dependent thereon, are drawn to a transgenic plant comprising "a cytokine in an amount of 0.1 ng to one milligram per one kilogram by fresh weight of the grown up transgenic plant". Applicant method steps are identical to those of Goodman, as discussed above. Applicant's starting materials are identical to Goodman's. Therefore, the percentage yield would have been an inherent property of the DNA construct used. If Applicant's percentage yields are different from that of Goodman, Applicant must have done something to make the yields different. It is suggested that Applicant amend the claims and include elements which would distinguish the claimed invention from Goodman.

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Accordingly Goodman anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 11-16, 18-21 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman, as discussed above, in view of Vogel et al, J Exper. Botany. 52, 1817-1826, 2001.

The teachings of Goodman are discussed above. Goodman does not teach further supplementation with trehalose. The addition of sugars to food is notoriously well known. The supplementation of food with trehalose, a sugar, is an obvious design variant and reflects design choices, which were well within the knowledge and skill of one of ordinary skill in the art and could be used with reasonable expectation of success. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

REMARKS

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
Patent Examiner
Art Unit 1638
March 21, 2004



Phuong T. Bui
PHUONG T. BUI
PRIMARY EXAMINER 3/22/04